

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

ROBERT D. WINDLE III and
GAIL WINDLE,

Plaintiffs,

vs.

SYNTHES USA PRODUCTS, LLC,
SYNTHES USA SALES, LLC, SYNTHES
(U.S.A.), INC., SYNTHES (U.S.A.), L.P.,
SYNTHES SPINE COMPANY, L.P.,
SYNTHES, INC., SYNTHES SPINE, INC.,
AND STEPHEN WESLEY WOLFE,

Defendants.

Civil Action No.: 11-cv-2591

**NOTICE OF REMOVAL OF DEFENDANTS SYNTHES USA PRODUCTS, LLC,
SYNTHES USA SALES, LLC, SYNTHES (U.S.A.) INC., SYNTHES (U.S.A.) L.P.,
SYNTHES SPINE COMPANY, L.P., SYNTHES, INC., AND SYNTHES SPINE, INC.**

Pursuant to 28 U.S.C. §§ 1441(a) and 1446, Defendants Synthes USA Products, LLC, Synthes USA Sales, LLC, Synthes (U.S.A.) Inc., Synthes (U.S.A.), L.P., Synthes Spine Company, L.P., Synthes, Inc., and Synthes Spine, Inc. (collectively the “Synthes Defendants”),¹ with full reservation of and without waiver of any and all defenses, objections, and exceptions, hereby file this Notice of Removal of this action from the County Court at Law 2 of Dallas County, Texas, Cause No. CC-11-0277-B (the “State Court Action”) to the United States District Court for the Northern District of Texas, Dallas Division. This Court has jurisdiction over this

¹ Synthes (U.S.A.) Inc., Synthes (U.S.A.), L.P., Synthes Spine Company, L.P., Synthes, Inc., and Synthes Spine, Inc. are not proper parties to this action. *See* Defs.' Answer and Verified Denial attached as Exhibit 25 to Exhibit A.

action based on diversity jurisdiction, 28 U.S.C. § 1332, and federal question jurisdiction, 28 U.S.C. § 1331. In support thereof, the Synthes Defendants show as follows:

I. THE REMOVED CASE

1. This products liability action arises out of the implantation of a Synthes ProDisc-C Total Disc Replacement device (“ProDisc-C”) by Kevin Gill, M.D. in Plaintiff Robert D. Windle, III on or about April 9, 2009 for treatment of joint breakdown, foraminal stenosis, and degenerative disc disease. *See* Pet. ¶¶ 37, 40.² Plaintiffs have pled eleven causes of action, including (1) strict liability in tort-products, *id.* ¶¶ 44-48; (2) negligence in tort-products liability, *id.* ¶¶ 49-54; (3) breach of express and implied warranties, *id.* ¶¶ 55-58; (4) breach of implied warranty of fitness for a particular purpose, *id.* ¶¶ 59-62; (5) violations of the Texas Deceptive Trade Practices Act (DTPA), *id.* ¶¶ 63-71; (6) common law negligence, *id.* ¶¶ 72-74; *id.* (7) assault, ¶¶ 75-76; (8) fraud, *id.* ¶¶ 77-80; (9) conspiracy, *id.* ¶¶ 81-84; (10) aiding and abetting, *id.* ¶¶ 85-88; (11) violation of the Civil Rights Act (Section 1983), *id.* ¶¶ 89-92; and have pled exemplary damages and loss of consortium damages, *id.* ¶¶ 93-95. The Synthes Defendants and Defendant Stephen Wesley Wolfe (“Defendant Wolfe” or “Mr. Wolfe”) deny all such allegations and deny that they, in any way, can be held liable for Plaintiffs’ alleged injuries and damages.

2. The State Court Action was commenced in the County Court at Law 2 of Dallas County, Texas on or about April 8, 2011 by Plaintiffs Robert D. Windle, III (“Mr. Windle”) and Gail Windle (“Mrs. Windle”) (collectively “Plaintiffs”) against the Synthes Defendants, Mr. Wolfe, a Synthes sales representative present at Mr. Windle’s implantation procedure, Defendant Kevin Gill, M.D., (“Dr. Gill”), Defendant University of Texas Southwestern Medical Center at

² A true and correct copy of Plaintiffs’ Original Petition (the “Petition”) is attached as Exhibit 2 to Exhibit A.

Dallas (UTSW), Defendant Zale Lipshy University Hospital (“Lipshy Hospital”), and Defendant Kevin Gill, M.D., P.A. (“Gill, P.A.”) (collectively the “Original Defendants”).

3. Plaintiffs served their Petition on the Original Defendants on various dates beginning on or about April 22, 2011.

4. On June 10, 2011, Defendants UTSW, Lipshy Hospital, and Dr. Gill were dismissed pursuant to Texas Civil Practice and Remedies Code § 101.106. *See* June 10, 2011 Orders.³

5. On September 1, 2011, Plaintiffs filed their Notice of Partial Nonsuit Without Prejudice, dismissing their claims against Defendant Gill, P.A. *See* Notice of Partial Nonsuit.⁴

6. The Defendants currently in this action are the Synthes Defendants and Mr. Wolfe.

II. PAPERS FROM REMOVED ACTION

7. As required by 28 U.S.C. § 1446(a) and Local Rule 81.1, attached as Exhibit A are: (1) an index of all documents included in Exhibit A; (2) a copy of the docket sheet in the State Court Action; and (3) all documents filed in the State Court Action, including all processes, pleadings, and orders.

III. DIVERSITY JURISDICTION AND IMPROPER JOINDER

A. The Removal Is Timely

8. The Original Defendants were served with a copy of Plaintiffs’ Petition on various dates beginning on or about April 22, 2011.

9. The Plaintiffs are residents of the State of Texas. *See* Pet. ¶¶ 2-3.

³ A true and correct copy of the State Court Action Orders dated June 10, 2011 (the “June 10, 2011 Orders”) are attached as Exhibits 33 and 34 to Exhibit A.

⁴ A true and correct copy of Plaintiffs’ Notice of Partial Nonsuit Without Prejudice dated September 1, 2011 (“Notice of Partial Nonsuit”) is attached as Exhibit 70 to Exhibit A.

10. Defendants Synthes (U.S.A.), Inc., Synthes (U.S.A.), L.P., and Synthes Spine, Inc. were organized under the laws of the State of Delaware and had their principal places of business in Pennsylvania. *See* Croft Decl. ¶¶ 5, 6, 8, App. A, Exh. 1.⁵ They were, therefore, citizens of the State of Delaware and the Commonwealth of Pennsylvania. 28 U.S.C. § 1332(c)(1). These entities, however, are no longer in existence and are not proper parties to this action. *See* Croft Decl. ¶¶ 5, 6, 8, App. A, Exh. 1. Thus, their citizenship may be disregarded.

11. Defendants Synthes USA Products, LLC, Synthes USA Sales, LLC, Synthes Spine Company, L.P., and Synthes, Inc. are organized under the laws of the State of Delaware and have their principal places of business in the Commonwealth of Pennsylvania. *See* Croft Decl. ¶¶ 3, 4, 7, App. A, Exh. 1. They are, therefore, citizens of the State of Delaware and the Commonwealth of Pennsylvania. 28 U.S.C. § 1332(c)(1).⁶

12. Defendant Wolfe, although a citizen of the State of Texas, *see* Pet. ¶¶ 11, is improperly joined and, therefore, his citizenship is disregarded. *Smallwood v. Illinois Cent. R.R. Co.*, 385 F.3d 568, 577-78 (5th Cir. 2004) (holding that if a defendant was improperly joined, his or her “existence is disregarded for purposes of determining diversity”).

13. Original Defendant UTSW is a state agency of the State of Texas. *See* Pet. ¶¶ 12. It is, therefore, a citizen of the State of Texas.

⁵ True and correct copies of the Declaration of David Croft (“Croft Decl.”) is attached as Exhibit 1 to Appendix A.

⁶ Regardless, Synthes Spine Company, L.P. and Synthes, Inc. are not proper parties to this action and, thus, their citizenship may be disregarded. *See* Defs.’ Answer and Verified Denial attached as Exhibit 25 to Exhibit A.

14. Original Defendant Lipshy Hospital is a state agency of the State of Texas. *See* Pet. ¶¶ 13; UTSW’s Original Ans. ¶ I.⁷ It is, therefore, a citizen of the State of Texas.

15. Original Defendant Dr. Gill is a citizen of the State of Texas. *See* Pet. ¶ 14.

16. Original Defendant Gill, P.A. is a Texas professional association. *See* Pet. ¶ 15. It is, therefore, a citizen of Texas.

17. Disregarding the citizenship of the improperly joined Defendant, Mr. Wolfe, of the Original Defendants, UTSW, Lipshy Hospital, Dr. Gill, and Gill, P.A. were non-diverse in relation to Plaintiffs.

18. On June 10, 2011, Original Defendants UTSW, Lipshy Hospital, and Dr. Gill were dismissed, leaving Original Defendant Gill, P.A. as the only remaining non-diverse Defendant. *See* June 10, 2011 Orders.

19. On September 1, 2011, Original Defendant Gill, P.A. was voluntarily nonsuited by Plaintiffs, creating complete diversity of citizenship between Plaintiffs and the Synthes Defendants, the only properly joined Defendants remaining in this action. *See* Notice of Partial Nonsuit.

20. Pursuant to 28 U.S.C. § 1446(b), “[i]f the case stated by the initial pleading is not removable, a notice of removal may be filed within thirty days after receipt by the defendant, through service or otherwise, of a copy of an amended pleading, motion, order or other paper from which it may first be ascertained that the case is one which is or has become removable” The Notice of Partial Nonsuit dismissing Defendant Gill, P.A. constitutes an “order or other paper” opening the thirty-day window during which the case may be removed. *See Strickert v.*

⁷ A true and correct copy of Lipshy Hospital’s Original Answer is attached as Exhibit 16 to Exhibit A.

THI of Tex. at Richardson, L.L.C., No. 3:08-CV-412-L, 2008, U.S. Dist. LEXIS 68407, at *8 (N.D. Tex. Aug. 27, 2008) (holding that the plaintiff's notice of nonsuit dismissing non-diverse defendant was an "other paper" giving rise to 30-day window to remove under 28 U.S.C. § 1446(b)).

21. Accordingly, because this Notice of Removal is filed within 30 days of the September 1, 2011 Notice of Partial Nonsuit dismissing the final remaining non-diverse Defendant, it is timely under 28 U.S.C. § 1446(b).

B. Diversity Jurisdiction Exists

22. The only remaining parties to this action are Plaintiffs, citizens of the State of Texas, the Synthes Defendants, citizens of the Commonwealth of Pennsylvania and the State of Delaware, and Mr. Wolfe, citizen of the State of Texas. *See* 28 U.S.C. § 1332.

23. Thus, Mr. Wolfe is the only non-diverse Defendant currently in this action. However, because Mr. Wolfe was improperly joined, his citizenship is disregarded and complete diversity of citizenship between Plaintiffs and Defendants exists.

24. Removal cannot be defeated by the improper joinder of a non-diverse defendant. *Wilson v. Republic Iron & Steel Co.*, 257 U.S. 92, 97 (1921). In this Circuit, a defendant is improperly joined if there is no "reasonable basis for predicting that state law might impose liability on the resident defendant[] under the facts alleged." *See Badon v. R.J.R. Nabisco, Inc.*, 236 F.3d 282, 286 (5th Cir. 2000); *see also Smallwood*, 385 F.3d at 573 (holding that a defendant is improperly joined where "there is no reasonable basis for the district court to predict that the plaintiff might be able to recover against an in-state defendant"). Under this standard, "[a] 'mere theoretical possibility of recovery under local law' will not preclude a finding of improper

joinder.” *Smallwood*, 385 F.3d at 573 n.9 (quoting *Badon v. RJR Nabisco, Inc.*, 236 F.3d 282, 286 n.4 (5th Cir. 2000)). Instead, there must be a “reasonable basis” for predicting the plaintiff might establish the non-diverse defendant’s liability on the pleaded claims before remand will be warranted. *Griggs v. State Farm Lloyds*, 181 F.3d 694, 699 (5th Cir. 1999).

25. To determine whether there is such a “reasonable basis” to predict that the plaintiff may recover, “a federal court may consider ‘summary judgment-type evidence such as affidavits and deposition testimony.’” *Griggs*, 181 F.3d at 700 (quoting *Cavallini v. State Farm Mutual Auto Ins. Co.*, 44 F.3d 256, 263 (5th Cir. 1995)).

26. In this case, Plaintiffs’ claims against Mr. Wolfe must be disregarded because “there is no reasonable basis for the district court to predict that [Plaintiffs] might be able to recover against [him].” *Smallwood*, 385 F.3d at 573.

27. Despite the various labels placed on Plaintiffs’ claims against Mr. Wolfe, they are all based on the allegation that Mr. Wolfe failed to warn regarding certain alleged risks related to Mr. Windle’s ProDisc-C. *See, e.g.*, Pet. ¶¶ 26-27. Plaintiffs cannot succeed in their claims against Mr. Wolfe because, as a sales representative for Synthes, he did not owe an independent duty to warn of the risks of ProDisc-C.

28. The Texas Supreme Court held that a company’s sales representative, as an employee, does not assume individual liability merely by participating in his or her employer’s purported failure to provide adequate information. *See Leitch v. Hornsby*, 935 S.W.2d 114, 117-18 (Tex. 1996); *see also In re: Diet Drugs Prod. Liab. Lit.* (“*In re Diet Drugs*”), MDL No. 1203, 2004 U.S. Dist. LEXIS 26754, at *7 (E.D. Pa. June 30, 2004) (citing to *Leitch* in holding that, under Texas law, the drug manufacturer’s sales representatives were not under an independent

duty to warn). As such, the sales representative of a medical device manufacturer does not owe a duty to warn as a “seller” for purposes of Texas product liability law. *See In re Diet Drugs*, MDL No. 1203, 2004 U.S. Dist. LEXIS 26754, at *28-29; *see also Morrow v. Wyeth*, 2005 WL 2621555 (S.D. Tex. Oct. 13, 2005) (holding that the sales representatives were fraudulently joined, because “[u]nder Texas law, both negligence generally and duty to warn specifically are duties of the corporation that do not create an independent duty in the employee”). Rather, it is “[the manufacturer] which [i]s ‘engaged in the business of distributing or otherwise placing, for any commercial purpose, in the stream of commerce for use or consumption a product or any component part thereof,’” that has the duty to warn. *See id.* (quoting Tex. Civ. Prac. & Rem. Code § 82.001(3)). Thus, “the general rule” in Texas is that pharmaceutical and medical device sales representatives do not owe a duty to warn independent of the manufacturers’ duty “because the [sales representatives] do not have [a] duty to research and ensure the safety [of the drug or device] separate from [the manufacturer’s] duty. *See Budd v. Wyeth, Inc.*, No. A-03-CA-465-SS, 2003 U.S. Dist. LEXIS 26778, at *10-11 (W.D. Tex. Sept. 17, 2003). Accordingly, district courts applying Texas law hold that there is “no reasonable possibility” that a plaintiff can recover against a sales representative for claims based on failure to warn, including misrepresentation claims. *See In re Diet Drugs*, MDL No. 1203, 2004 U.S. Dist. LEXIS 26754, at *32 (noting that “altogether, sales representatives have been dismissed or found to be fraudulently joined in 129 cases before Texas federal courts as of April 7, 2004”).

29. Indeed, federal courts in the Fifth Circuit have repeatedly held in drug and medical device products liability cases that non-diverse sales representatives and health care providers have been fraudulently joined. *See, e.g., Morrow v. Wyeth*, B-05-209, 2005 U.S. Dist. LEXIS

43194, at *17-18 (S.D. Tex. Oct. 13, 2005) (sales representatives were fraudulently joined, because “[u]nder Texas law, both negligence generally and duty to warn specifically are duties of the corporation that do not create an independent duty in the employee” and there were no specific allegations imposing such a duty in the case); *Tantillo v. Cordis Corp.*, No. 04-2005, 2004 U.S. Dist. LEXIS 19615, at *4-5 (E.D. La. Sept. 30, 2004) (holding hospital was improperly joined because it could not be liable as a “seller” under the Louisiana product liability law); *Lizana v. Guidant Corp.*, No. 1:03cv254GRo, 2004 U.S. Dist. LEXIS 27623, at * 8 (S.D. Miss. Jan. 21, 2004) (sales representative was fraudulently joined where “Plaintiffs have presented no evidence to support the assertion that the pacemaker was in fact malfunctioning at the time [the representative] made the statement regarding its performance”); *Walker v. Medtronic, Inc.*, 2003 No. 1:03CV74-D-D, 2003 U.S. Dist. LEXIS 26549, at *10 (N.D. Miss. June 4, 2003) (finding medical device sales representative fraudulently joined where the complaint did not “specifically allege how [the sales representative] directly participated in or authorized the commission of the tort of fraudulent misrepresentation or how her alleged liability is based on her own individual wrongdoing”).

30. Thus, as a matter of Texas law, Plaintiffs cannot succeed in their claims against Mr. Wolfe because, as a sales representative, he is not a “seller” for product liability purposes and he did not owe an independent duty to warn of the risks and dangers of ProDisc-C. *See Budd*, No. A-03-CA-465-SS, 2003 U.S. Dist. LEXIS 26778, at *10-11.

31. Moreover, the uncontroverted evidence demonstrates that there is no basis for imposing a duty to warn upon Mr. Wolfe. Mr. Wolfe testified that his job responsibilities include ensuring products are available for his physician customers during implantation and

explantation surgeries and providing technical support related to the device only. *See* Wolfe Dep. at 9-8, App. A, Exh. 2.⁸ The technical support he provides is comprised of supplying information related to the availability of sizes and dimensions of the products. *Id.* at 10. It is not his responsibility to communicate particular warnings to physicians. *Id.* at 97-98. Rather, surgeons are provided all of the information and warnings they need through the surgeon-to-surgeon training they receive on implantation of ProDisc-C. *Id.* at 124. Moreover, he never discusses risks and benefits of ProDisc-C surgery with patients because that would be beyond his expertise. *Id.* at 123. Specifically, he has never communicated with or had any interaction with Mr. Windle. *Id.* at 45, 100-01.

32. Neither can Plaintiffs create a duty to warn owed by Mr. Wolfe by alleging that Mr. Wolfe engaged in the unauthorized practice of medicine. *See* Pet. ¶¶ 72-73. First, any claim premised upon the unauthorized practice of medicine fails as a matter of law because there is no private cause of action in Texas for the unauthorized practice of medicine. *See Aguirre v. Tristar Risk Mgmt.*, No. C-10-394, 2011 U.S. Dist. LEXIS 6415, at *6. *14 (S.D. Tex. Jan. 24, 2011) (dismissing the plaintiff's claim because "the Court [] found no cases allowing for a private cause of action to be brought for the unauthorized practice of medicine under *Section 165.153*"); *see also Cassidy v. Team Health, Inc.*, No. 01-08-00324-CV, 2009 WL 2231217 (Tex. App. -- Houston[1st Dist.] July 23, 2009) (finding no private cause of action for the "corporate practice of medicine" under Texas law). Second, the uncontroverted evidence demonstrates that Mr. Wolfe did not diagnose or treat Mr. Windle or otherwise engage in the practice of medicine. *See* Wolfe Dep. at 41-45, App. A, Exh. 2. Mr. Wolfe testified repeatedly that his involvement

⁸ Relevant excerpts from the Deposition of Stephen Wesley Wolfe, are attached as Exhibit 2 to Appendix A.

related to Mr. Windle's spinal surgeries was limited to providing Dr. Gill with information regarding the availability of sizes of the device and ensuring that all available sizes of the device for Dr. Gill to choose from were on hand. *See id.*

33. Because there is no "reasonable basis" to conclude that Plaintiffs can establish a cause of action against Mr. Wolfe, Mr. Wolfe was improperly joined. *See Griggs*, 181 F.3d at 699.

34. Disregarding the citizenship of Mr. Wolfe due to his improper joinder, *see Smallwood*, 385 F.3d at 577-78, complete diversity exists in this case because Plaintiffs are Texas citizens and the Synthes Defendants are citizens of the Commonwealth of Pennsylvania and the State of Delaware, *see* 28 U.S.C. § 1332.

C. The Amount-In-Controversy Exceeds \$75,000

35. This action satisfies the amount-in-controversy requirement. *See* 28 U.S.C. § 1332. While Plaintiffs' Petition does not allege the specific amount of damages sought therein, the amount in controversy exceeds the jurisdictional threshold. When there is no specific damage amount alleged, the district court must "examine the complaint to determine whether it is 'facially apparent' that the claims exceed the jurisdictional amount." *See St. Paul Reinsurance Co., Ltd. v. Greenberg*, 134 F.3d 1250, 1253 (5th Cir. 1998); *see also White v. FCI USA, Inc.*, 319 F.3d 672, 674-6 (5th Cir. 2003) (finding it facially apparent that plaintiff's wrongful termination claim exceeded \$75,000 based on claims for loss of pay, fringe benefits, impaired earning capacity, harm to credit, emotional distress, attorney fees, punitive damages, etc.); *Luckett v. Delta Airlines, Inc.*, 171 F.3d 295, 298 (5th Cir. 1999) (finding it "facially apparent" that plaintiff's claim exceeded \$75,000 where plaintiff alleged property damage, travel expenses,

an emergency ambulance trip, a six day stay in the hospital, pain and suffering, humiliation, and temporary inability to perform housework following hospitalization).

36. Here, Plaintiffs allege that Mr. Windle is a quadriplegic as a result of Defendants' alleged conduct, claiming damages for Mr. Windle's alleged "severe personal injuries, including permanent bodily impairment, disfigurement, loss of earning capacity in the past, and loss of earning capacity in the future," . . . "physical pain and mental anguish" in the past and future, "medical charges and life care plan expenses" in the past and future. *See* Pet. ¶¶ 43, 93. Plaintiffs further claim damages for Mrs. Windle's alleged "loss of support; loss of consortium and companionship." *See id.* ¶ 95. In addition, Plaintiffs claim "punitive and/or exemplary damages." *See id.* ¶¶ 94-95.

37. Thus, although the Synthes Defendants and Mr. Wolfe deny any liability for Plaintiffs' alleged injuries and damages, it is evident from the face of the Petition that the amount in controversy exceeds \$75,000, excluding interest and costs. *See* 28 U.S.C. § 1332.

D. Consent of All Defendants

38. Other than the Synthes Defendants, the only remaining Defendant is Mr. Wolfe.

39. Because Mr. Wolfe was improperly joined, his consent to removal is not required. *See Jernigan v. Ashland Oil Co.*, 989 F.2d 812, 815 (5th Cir. 1993) (requiring consent to removal "by improperly or fraudulently joined parties would be nonsensical").

40. Nonetheless, Mr. Wolfe, who is represented by the undersigned counsel, consents to the removal of this action on these grounds. *See* Wolfe Consent.⁹

⁹ The Consent of Defendant Stephen Wesley Wolfe ("Wolfe Consent") is attached as Exhibit 3 to Appendix A.

IV. FEDERAL QUESTION JURISDICTION

A. Removal Is Timely

41. As of its initial service upon the Original Defendants, federal question jurisdiction existed based on the nature of Plaintiffs' claims. *See Chertkov v. TPLC, Inc.*, 916 F. Supp. 608, 611 (N.D. Tex. 1996).

42. As such, on May 9, 2011, counsel for the Synthes Defendants and Mr. Wolfe requested that Defendant Dr. Gill consent to removal of the action to federal court. *See Wahby Decl.* ¶ 2, App. A, Exh. 4.¹⁰ However, counsel for Dr. Gill declined to consent to removal. *See id.* Consequently, because removal requires the consent of all properly joined Defendants, this action was not initially removable. *See Doe v. Kerwood*, 969 F.2d 165, 166 (5th Cir. 1992).

43. On June 10, 2011, Dr. Gill, UTSW, and Lipshy Hospital were dismissed, leaving Defendant Gill, P.A. as the only remaining non-consenting Defendant. *See* June 10, 2011 Orders.

44. On July 6, 2011, counsel for the Synthes Defendants and Mr. Wolfe requested that counsel for Defendant Gill, P.A. consent to removal to federal court. *See Lockard Decl.* ¶ 2, App. A, Exh. 5.¹¹ However, counsel for Defendant Gill, P.A. declined to consent to removal. *See id.*

45. On September 1, 2011, Defendant Gill, P.A. was voluntarily nonsuited by Plaintiffs, leaving the Synthes Defendants and Mr. Wolfe as the only remaining Defendants. *See* Notice of Partial Nonsuit. Because Mr. Wolfe, through the undersigned counsel, consents to removal on

¹⁰ The Declaration of Peter Wahby ("Wahby Decl.") is attached hereto as Exhibit 4 to Appendix A.

¹¹ The Declaration of Victoria Lockard ("Lockard Decl.") is attached hereto as Exhibit 5 to Appendix A.

these grounds, Plaintiffs' September 1, 2011 nonsuit allows for removal by dismissing the only remaining non-consenting Defendant.

46. Pursuant to 28 U.S.C. § 1446(b), "[i]f the case stated by the initial pleading is not removable, a notice of removal may be filed within thirty days after receipt by the defendant, through service or otherwise, of a copy of an amended pleading, motion, order or other paper from which it may first be ascertained that the case is one which is or has become removable" The Notice of Partial Nonsuit dated June 10, 2011 constitutes an "order or other paper" opening the thirty-day window during which the case may be removed. *See Parker v. County of Oxford*, 224 F. Supp. 2d 292, 295 (D. Me. 2002) (holding that the dismissal of the non-consenting defendant was an "other paper" giving rise to 30-day window to remove under 28 U.S.C. § 1446(b)).

47. Accordingly, because this Notice of Removal is filed within 30 days of the September 1, 2011 Notice of Partial Nonsuit dismissing the only remaining non-consenting Defendant, it is timely under 28 U.S.C. § 1446(b).

B. Federal Question Jurisdiction Exists

1. Plaintiffs' State Law Claims Are Federal in Nature

48. Although this matter is properly removable to this Court based on diversity grounds alone, removal of this action is also proper on the grounds of federal question based on 28 U.S.C. § 1331 and the Supreme Court's 2005 ruling in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005). This lawsuit requires resolution of issues premised on the application of federal law and regulations. Federal issues are actually in dispute, the federal issues are substantial and the exercise of jurisdiction by this Court is consistent with

congressional judgment about the sound division of labor between the state and federal courts. *See Grable*, 545 U.S. 308 (affirming removal based on federal question jurisdiction even though Congress did not provide private right of action in statute giving rise to substantial federal question; clarifying impact of *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986)); *see also Chertkov v. TPLC, Inc.*, 916 F. Supp. 608, 611 (N.D. Tex. 1996) (holding that “an exception to the well-pleaded complaint rule has been created in certain areas in which Congress has so completely pre-empted a particular area that any civil complaint raising this select group of claims is necessarily federal in character”).

49. The *Grable* Court held that federal question jurisdiction does not require the plaintiff to have asserted a federal cause of action and that a case asserting only state law causes of action is removable if it raises a substantial federal question that is in dispute. *See id.* at 316-20. Further, for cases involving a substantial federal question, under the artful pleading doctrine, “a plaintiff may not defeat removal by omitting to plead necessary federal questions.” *Rivet v. Regions Bank*, 522 U.S. 470, 475 (1998). Rather, “[i]f a court concludes that a plaintiff has ‘artfully pleaded’ claims in this fashion, it may uphold removal even though no federal question appears on the face of the plaintiff’s complaint.” *Id.*

50. A substantial federal question giving rise to federal question jurisdiction exists where:

(1) resolving a federal issue is necessary to resolution of the state-law claim; (2) the federal issue is actually disputed; (3) the federal issue is substantial; and (4) federal jurisdiction will not disturb the balance of federal and state judicial responsibilities.

Clauer v. Heritage Lakes Homeowners Ass'n, No. 4:09-cv-560, 2010, at *6, 2010 U.S. Dist. LEXIS 8947 (E.D. Tex. 2010) (quoting *Singh v. Duane Morris LLP*, 538 F.3d 334, 338 (5th Cir. 2008)).

51. As stated in Plaintiffs' Petition, the basis for all of Plaintiffs' claims against Defendants is that ProDisc-C was labeled in "direct violation or contravention" to FDA requirements because the Patient Information Brochure did not warn "that the product was not safe or effective for patients with prior fusion surgery at an adjacent vertebral level or the level to be treated." *See, e.g.*, Pet. ¶¶ 28, 44. Because ProDisc-C is a Class III medical device scrutinized and approved by the Food and Drug Administration (FDA) during the rigorous Premarket Approval (PMA) process, all ProDisc-C labeling, including the Patient Information Brochure, must comply with federal requirements imposed through the ProDisc-C PMA and federal regulations.

52. Thus, the face of Plaintiffs' Petition raises substantial federal issues related to FDA regulation of ProDisc-C, and, in particular, FDA requirements for the ProDisc-C labeling imposed through the PMA process and FDA regulations and guidances related to medical device labeling intended for lay persons. *See, e.g.*, 21 C.F.R. 801 Subpart A; 21 C.F.R. § 801.109; FDA Guidance: Medical Device Patient Labeling (2001).

53. Indeed, the Central District of California found that a nearly identical state law strict liability claim involving ProDisc-C "necessarily depend[ed] on [the] resolution of a substantial question of federal law, in that federal law [wa]s a necessary element of one of the well-pleaded . . . claims." *See Reider-Gordon v. Synthes Spine Co., L.P.*, No. CV 10-00641 ODW, 2010 U.S. Dist. LEXIS 69343, at *12, 17-18 (quoting *Christianson v. Colt Indus. Operating Corp.*, 486

U.S. 800, 808 (1988)). In *Reider-Gordon*, the plaintiff's strict liability claim alleged that "ProDisc was not manufactured or labeled as approved by the FDA" and that the Defendants were "strictly liable because they ha[d] circumvented the Pre-Marketing approval process set out by the FDA." *Id.* at *17 (internal quotations omitted). The Court concluded that "[b]ased on Plaintiff's own allegations, her right to relief, at least with respect to the strict liability claim, necessarily depends on resolution of the issue of whether Defendants circumvented the premarketing approval process set out by the FDA." *Id.* at *18. Thus, the Court held that it could properly exercise federal question jurisdiction over the strict liability claim and supplemental jurisdiction over the remaining state claims. *Id.*

54. Here, like in *Reider-Gordon*, Plaintiffs' "right to relief . . . necessarily depend[] on resolution of the issue of whether Defendants circumvented the premarketing approval process set out by the FDA." *See id.* For example, Plaintiffs' strict liability claim here alleges that "because [ProDisc-C] was inappropriately labeled by the Synthes Defendants and marketed by all of the Defendants . . . [ProDisc-C] was defective and unsafe for its intended use, *in direct violation or contravention of the terms and conditions of the product's approval as outlined or specified in the PMA.*" *See* Pet. ¶ 44 (emphasis added). Plaintiffs further claim that Defendants' "*circumvention of the warning process required by the FDA . . . caused the Synthes Defendants and Wolfe to market in the United States a device that is inherently dangerous to particular patients without warning those patients of the danger(s).*" *Id.* ¶ 47 (emphasis added). Thus, on the face of Plaintiffs' Petition, an essential element of their claims is the interpretation of "the terms and conditions" of federal requirements. *See id.* ¶ 44. In other words, in order to recover under any theory, Plaintiffs must prove that Defendants violated federal requirements.

Consequently, Plaintiffs' claims as stated in the Petition require the determination of substantial federal issues, the determination of which by this Court would not disturb any congressionally approved balance of federal and state judicial responsibilities. *See Clauer*, No. 4:09-cv-560, 2010 U.S. Dist. LEXIS 8947, at *6.

55. Defendants dispute Plaintiffs' allegations and specifically dispute Plaintiffs' claim that they had any duty under federal law to include warnings not contained in the FDA-approved ProDisc-C Patient Information Brochure. Determination of these federal issues is necessary to the resolution of all of Plaintiffs' claims against Defendants.

56. Thus, Plaintiffs' claims as alleged on the face of the Petition constitute a substantial federal question because the claims raise federal issues, determination of the federal issues is necessary to the resolution of the claims, the federal issues are actually disputed, the federal issues are substantial and this Court can entertain the claims without disturbing any congressionally approved balance of federal and state judicial responsibilities. *See Clauer*, No. 4:09-cv-560, 2010 U.S. Dist. LEXIS 8947, at *6.

57. As a result of the federal questions raised against Defendants, this Court has original federal question jurisdiction over the subject matter of this civil action pursuant to 28 U.S.C. § 1331, and this civil action is properly removed to this Court under 28 U.S.C. §§ 1441 & 1446.

58. In addition, all of Plaintiffs' claims arise from the same nucleus of operative fact: the implantation of an allegedly defective ProDisc-C device in Mr. Windle on or about April 9, 2009. *See* Pet. ¶ 40.

59. Thus, even if not all of Plaintiffs' claims raise substantial federal questions, this Court may exercise supplemental jurisdiction over the remaining state law claims pursuant to 28 U.S.C. § 1441(c). *See United Mine Workers v. Gibbs*, 383 U.S. 715, 725 (1966).

2. Plaintiffs' Section 1983 Claim Against Defendant Wolfe Arises Under the Laws of the United States

60. Plaintiffs' cause of action for the alleged violation of the Civil Rights Act (42 U.S.C. § 1983),¹² Pet. ¶¶ 89-91, arises under the laws of the United States and, therefore, this Court has federal question jurisdiction over that claim. *See* 28 U.S.C. § 1331.

61. All of Plaintiffs' claims, including the Section 1983 claim arise from the same nucleus of operative fact: the implantation of an allegedly defective ProDisc-C device in Mr. Windle on or about April 9, 2009. *See, e.g.*, Pet. ¶ 91.

62. Consequently, pursuant to 28 U.S.C. § 1441(c), this Court may exercise supplemental subject matter jurisdiction over the remaining state law claims against the Synthes Defendants and Defendant Wolfe because the state law claims share a common nucleus of operative fact with the Section 1983 claim. *See Gibbs*, 383 U.S. at 725.

C. Consent of All Defendants

63. Defendant Wolfe, who is represented by the undersigned counsel, consents to the removal of this action on these grounds. *See* Wolfe Consent.

V. REMOVAL IS PROPER

64. No previous application has been made for the relief requested herein.

¹² Plaintiffs' Section 1983 claim is against the "Medical Defendants." *See* Pet. ¶ 89. Plaintiffs include Mr. Wolfe in their identification of the "Medical Defendants" and assert that at all relevant times, Mr. Wolfe was an employee of the Synthes Defendants. *See* Pet. ¶ 31. Defendants deny that Mr. Wolfe is a "Medical Defendant" and deny that Mr. Wolfe or the Synthes Defendants can be held liable for the alleged conduct of Dr. Gill or any of the Original Defendants.

65. Venue is proper in this Court because the action is being removed from the County Court at Law 2 of Dallas County, Texas, which lies within the United States District Court for Northern District of Texas, Dallas Division. *See* 28 U.S.C. §§ 124(a)(1), 1446(a).

66. Consequently, the Synthes Defendants may remove the State Court Action to this Court in accordance with the provisions of 28 U.S.C. § 1441(a) because: (i) this action is a civil action pending within the jurisdiction of the United States District Court for the Northern District of Texas; and (ii) complete diversity of citizenship exists between Plaintiffs and the properly joined Defendants and the amount in controversy requirement is met.

67. In addition, the Synthes Defendants may remove the State Court Action to this Court in accordance with the provisions of 28 U.S.C. § 1441(a) because: (i) this action is a civil action pending within the jurisdiction of the United States District Court for the Northern District of Texas; and (ii) this action involves a federal question.

68. If any question arises as to the propriety of the removal of this action, the Synthes Defendants request the opportunity to brief any disputed issues and to present oral argument in support of their position that this case is properly removable.

69. Nothing in this Notice of Removal shall be interpreted as a waiver or relinquishment of the Synthes Defendants' or Mr. Wolfe's rights to assert any defenses including, without limitation, the defenses of (1) lack of jurisdiction over the person, (2) improper venue and/or forum non conveniens, (3) insufficiency of process, (4) insufficiency of service of process, (5) improper joinder of claims and/or parties, (6) failure to state a claim, (7) failure to join an indispensable party(ies), or (8) any other procedural or substantive defense available under state or federal law.

VI. CERTIFICATE OF INTERESTED PERSONS

70. Separately signed certificates of interested persons for each of the Synthes Defendants that comply with Local Rule 3.1(c) and 3.2(e) are filed concurrently herewith.

VII. FILING OF REMOVAL PAPERS

71. Pursuant to 28 U.S.C. § 1446(d), written notice of the removal of this action has been given simultaneously to Plaintiffs' counsel and a Notice of Removal to Federal Court is simultaneously being filed with the County Court at Law 2 of Dallas County, Texas.

VIII. JURY DEMAND

72. Plaintiffs and Defendants demanded a trial by jury in the State Court Action.

WHEREFORE, the Synthes Defendants hereby remove the above-captioned action from the County Court at Law 2 of Dallas County, Texas and request that further proceedings be conducted in this Court as provided by law.

Dated: September 30, 2011

Respectfully submitted,

By: /s/ P. William Stark

Peter S. Wahby
State Bar No. 24011171
wahbyp@gtlaw.com
P. William Stark
State Bar No. 24046902
starkb@gtlaw.com
GREENBERG TRAURIG LLP
2200 Ross Avenue, Suite 5200
Dallas, Texas 75201
Tel: (214) 665-3600
Fax: (214) 665-3601

Lori G. Cohen
Pro Hac Vice Application to be filed
Christiana C. Jacxsens
Pro Hac Vice Application to be filed
GREENBERG TRAURIG LLP
The Forum
3290 Northside Parkway, Suite 400
Atlanta, Georgia 30327
Tel: (678) 553-2100
Fax: (678) 553-2386

**ATTORNEYS FOR DEFENDANTS
SYNTHES USA PRODUCTS, LLC,
SYNTHES USA SALES, LLC,
SYNTHES (USA) INC., SYNTHES
(USA) L.P., SYNTHES SPINE
COMPANY, L.P., SYNTHES, INC.,
SYNTHES SPINE, INC. AND
STEPHEN WESLEY WOLFE**

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing instrument has been forwarded to all counsel of record, via certified mail, return receipt requested, on this 30th day of September, 2011, and addressed as follows:

Kenneth Chaiken
Robert L. Chaiken
Carrie E. Putterman
CHAIKEN & CHAIKEN, P.C.
One Galleria Tower
13355 Noel Road, Suite 600
Dallas, Texas 75240

/s/ P. William Stark
P. William Stark

ATL 18,286,276 3